UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, Plaintiffs, vs. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL Defendants.	Civil Action No. 19-12107 (KM) (ESK) Motion Date: Apr. 6, 2021 *Oral Argument Requested* *Document Electronically Filed*

DEFENDANTS' REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS SECOND AMENDED COMPLAINT

Jeffrey J. Greenbaum
Gregory E. Reid
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
Phone: (973) 643-7000

Gordon D. Todd (*pro hac vice*)
Kimberly Leaman (*pro hac vice*)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005

Attorneys for Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
Phone: (973) 757-1100

Jack E. Pace III (*pro hac vice)*
Alison Hanstead (*pro hac vice*)
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020-1095

Peter J. Carney (*pro hac vice*)
Adam M. Acosta (*pro hac vice*)
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005-3807

Kevin M. Bolan (*pro hac vice*)
WHITE & CASE LLP
75 State Street
Boston, MA 02109-1814
Telephone: (617) 979-9311

Attorneys for Defendant
BTG International Limited

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Other Authorities

PRELIMINARY STATEMENT

Defendants' Initial Brief presents two grounds for dismissal: (1) the prior public disclosure of Relator's claims; and (2) Relator's failure to plead necessary elements of an FCA claim. Relator's Opposition ("Opp.") cures neither. As to the first, his convoluted construction of the public disclosure bar manufactures ambiguity where there is none by reading words in and out of the statute. Relator struggles mightily to exclude from the bar *any* disclosure in *any* patent-related hearing or publication because he knows his allegations and transactions were disclosed through both. The bar prevents "'opportunistic' litigation" by relators who repurpose publicly available information, and Relator's cramped construction of the bar would impermissibly constrict its "generally broad scope." *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 408, 413 (2011). As to the second, Relator advances unsupported theories of FCA liability untethered from any claim for payment. His theories would reach any allegation of "fraud" touching the federal Government, no matter how attenuated, and cannot be reconciled with *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). Despite three tries, Relator's allegations remain fatally deficient. The SAC should be dismissed with prejudice.

I. THE PUBLIC DISCLOSURE BAR PRECLUDES RELATOR'S CLAIMS

Relator concedes that he prepared the SAC based on information "pieced … together" from public hearings and reports including patent prosecutions, *inter partes review* challenges, and media reports. Opp. 10 n.4, 21–22; Initial Brief ("Br.") 7–21. These same disclosures came through enumerated channels and included Relator's essential allegations. The bar thus attaches.

A. The Transactions And Allegations Underlying Relator's Claims Were Publicly Disclosed Through Enumerated Channels.

As amended in 2010, the FCA details three distinct channels through which a disclosure must be made to trigger the bar. 31 U.S.C. §3730(e)(4)(A)(i)–(iii). Relator contends that the

federal hearings and reports from which he cribbed his facts do not count because the United States was not a "party" to any of them. Nor, he further contends, do the publications he consulted count because they were not traditional journalistic sources. Relator's construction of the bar, however, lacks support and runs contrary to the weight of authority. All of the disclosures Defendants identified were through appropriate channels and support application of the public disclosure bar.

Boiled to its essence, Relator's 14-page, meandering discussion of the bar reduces to the following: (1) patent proceedings are "hearings" within Channel (i); (2) patent proceedings might also be an "other Federal … hearing" under Channel (ii); (3) but Channel (i) hearings trigger the bar only where Government is a party; (4) if patent proceedings are Channel (ii) hearings, that would undercut the federal party requirement in Channel (i); (5) therefore, Channel (ii) "other federal … hearings" cannot be read as written, but must also be constrained by Channel (i)'s party restriction. Opp. 4–8; 11–19.

Reduced further, Relator perceives an ambiguity between Channels (i) and (ii) and cured it by reading *into* the statute words Congress omitted, and reading *out of* the statute words Congress did include. He thus urges the Court to violate two fundamental rules of statutory construction. First, a "[c]ourt may not narrow a provision's reach by inserting words Congress chose to omit." *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020). Relator does that by reading the government-party restriction from Channel (i) into Channel (ii) (and Channel (iii) for that matter, *see* Opp. 21). Opp. 13–14. Congress knew well how to include such a limit; it did so in Channel (i); it did not do so in Channel (ii). Second, statutes "ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (cleaned up). Yet, in trying to stuff all agency proceedings exclusively into Channel (i), Relator reads out of the statute Channel (ii)'s

inclusion of GAO and "other … Federal" hearings.

That Relator's "fix" requires violating two cardinal rules of construction exposes Relator's erroneous interpretation. A need to constrain Channel (ii) to protect Channel (i) arises only if Channels (i) and (ii) cover generally the same hearings. Congress used the word "hearing" in both Channels, and the same word in the same statute often keeps the same meaning, *see Env't Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007). Yet "[a] given term in the same statute may take on distinct characters from association with distinct statutory objects calling for different implementation strategies." *Id.* The textual evidence here shows that Channels (i) and (ii) speak generally to different sorts of hearings. Br. 15–17.

First, Congress purposefully divided the bar into three sections, powerful evidence that each does independent work. Br. 14–16. Second, statutory text is known by the company it keeps, *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 320 (2014), and here each "hearing" has vastly different companions. Channel (i) covers "Federal criminal, civil, or administrative hearings" whereas Channel (ii) covers "congressional, [GAO], or other Federal … hearing[s]." Third, "it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Congress's decision to restrict hearings to government-party matters in Channel (i) but not (ii) should be respected, not undone.

Read as "an harmonious whole," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), the text shows that Channels (i) and (ii) cover generally different hearings, and a hearing may come within Channel (ii) without implicating Channel (i)—or vice versa—at all. Channel (i) covers adversarial, adjudicative proceedings to which the Government is a party, whereas Channel (ii) covers federal investigative, inquisitorial, and other similar non-adjudicative hearings at which the Government receives and considers information in the performance of its

various governance duties. Br. 14–17. The government-party restriction excludes from Channel (i) private civil disputes from which the Government is unlikely to learn facts. Channel (ii) needs no such restriction as the Government actively participates in every such hearing. Br. 15–16.

Relator's piecemeal responses promote a discordant reading. Relator points to commentary from statutory "architects," but this commentary predates the 2010 Amendments by over a decade. Opp. 4–8. In fact, the 2010 Amendments have no meaningful legislative history. *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 299 (3d Cir. 2016); *Silbersher v. Valeant Pharms. Int'l, Inc.*, 445 F. Supp. 3d 393, 404 (N.D. Cal. 2020), *appeal docketed*, No. 20-16176 (9th Cir. June 16, 2020).

Next, Relator argues that by replacing "administrative … hearing" with "Federal … hearing" in Channel (ii), while leaving "administrative hearing" in Channel (i), Congress intended to place *all* agency proceedings in Channel (i). Opp. 6. Not so. First, the change in Channel (ii) excluded myriad state hearings that had been read into "administrative … hearing," most notably in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 559 U.S. 280 (2010). Second, looking at the text of Channel (i), although "administrative hearing" standing alone might be read broadly, "criminal, civil, or administrative hearings" in conjunction strongly indicates adjudicative proceedings. Lastly, even as amended, Channel (ii) includes "GAO or other Federal hearing[s]," which plainly includes some agency hearings.

Lastly, Relator contrives his "PACER Trap," Opp. 21, arguing that if PACER filings were Channel (ii) federal reports or hearings, that would eviscerate Channel (i)'s government-party restriction, and therefore both channels should exclude electronic dockets generally. Opp. 12–13, 20–21. The only thing trapped, however, is Relator's logic. PACER is the federal judiciary's mechanism for reporting adjudicative proceedings, its contents all come within Channel (i), and is

therefore indisputably subject to Channel (i)'s government-party restriction. Filings from a case to which the Government *is not* a party do not become Channel (ii) reports simply by being published on PACER; and filings published on PACER from cases to which the Government *is* a party do nonetheless invoke the bar. This does not speak either way to the treatment of any other federal docket. In other words, the "PACER Trap" is a red herring.

1. Patent Prosecutions And IPRs Are Federal Hearings That Trigger the Bar.

Once Channels (i) and (ii) are properly construed, the rest of the analysis falls into place. Patent prosecutions plainly are not hearings within Channel (i). They are not adjudicative in any sense and do not have "parties"; rather, they are inquisitorial hearings within Channel (ii). A petitioner appears before the PTO and asks it to exercise its statutory authority to extend a government benefit. A patent examiner "reviews an applicant's patent claims, considers the prior art, and determines whether each claim meets the applicable patent law requirements." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136–37 (2016); *see also* 37 C.F.R. §1.104(a)(1) (examiners' duties). Examiners must consider certain information provided by the applicant and document their work. *See* 37 C.F.R. §1.97(b).[1] Finally, the examiner reports their conclusions regarding patentability to the applicant and the public. *See id.* §1.311; MPEP §1303.

IPRs follow from patent prosecutions. As the Supreme Court recently made clear, in an IPR, the PTO exercises "executive power" to "reconsider whether existing patents satisfy the novelty and nonobviousness requirements for inventions." *United States v. Arthrex, Inc.*, No. 19-1434, slip op. at 3–4 (U.S. June 21, 2021); *id.* at 9, 10, 15. The Supreme Court thus confirmed the Federal Circuit's explanation that in an IPR, the PTO "act[s] as the United States in its role as a

[1] PTO, *Manual of Patent Examining Procedure* ("MPEP") §609.01 (9th ed. 2020) (examiner must indicate whether a reference was considered); *id.* §704.14 ("examiner must consider all the information that is submitted" in response to a request for information); *id.* §704.14(b) (same).

superior sovereign to reconsider a prior administrative grant." *Saint Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018); *accord Regents of Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327 (Fed. Cir. 2019). And in *Arthrex*, the Court clarified that because the PTAB panel is wielding executive power and making an executive agency decision, that decision must be subject to review and reversal by the PTAB Director, a Principal Officer of the United States. *See Arthrex*, slip op. at 19–23 (plurality); *id.* Op. of Breyer, J., at 7. An IPR is thus best understood as a Channel (ii) inquisitorial hearing to gather facts in furtherance of the agency's statutory duties.

As explained in our Initial Brief, IPRs *also* bear hallmarks of Channel (i) adjudicatory hearings to which the Government is a party. IPRs are in no sense purely private litigation. Br. 17–19. To the contrary, an IPR may proceed only with the PTAB's approval. That the Director has elected to devolve this determination to inferior officers within the agency does not strip it of its executive nature. *Contra* Opp. 15. Institution decisions are a discretionary and unappealable "political responsibility," *Saint Regis*, 896 F.3d at 1327, not a "judicial determination," as Relator contends, Opp. 15. Relator argues nonetheless that the Government is not "the protagonist" in an IPR. Opp. 14–15. But in instituting an IPR, the agency acts like a prosecutor, acting on a third-party report, initiating a proceeding to re-evaluate the agency's own prior executive action. IPRs are concerned with "public rights" and are "in key respects a proceeding *between* the government and the patent owner." *Regents of Univ. of Minn.*, 926 F.3d at 1339 (emphasis added). They are thus distinct from private judicial or administrative litigation. *Saint Regis*, 896 F.3d at 1327–28.[2]

Arthrex makes clear that an IPR is an inquisitorial exercise of executive power naturally

[2] *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853 (2019), and *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), are not to the contrary. In *Return Mail*, the Court ruled that the Government may not initiate an IPR, 139 S. Ct. at 1867, but that does not make the IPR, once initiated, any less inquisitorial. In *SAS Institute*, the Court determined that the PTO must consider all or none of the claims before it, 138 S. Ct. at 1355, which again did not alter the fundamental nature of the PTO's reconsideration of its prior grant.

resting in Channel (ii). An IPR also could be a Channel (i) hearing. Br. 17–19. That the statutory public disclosure bar does not explicitly mention IPRs is hardly surprising given that Congress invented the IPR—an entirely novel proceeding—in 2011, after its 2010 revisions to the public disclosure bar. Every IPR puts the federal Government squarely on notice of all facts disclosed therein, triggering the public disclosure bar consistent with the statutory goals and the 2010 Amendments. The answer cannot be, as Relator suggests, that IPRs trigger neither channel.

2. PTO Publications On PAIR Are Federal Reports That Trigger The Bar.

Channel (ii) also includes Federal "report[s]." 31 U.S.C. §3730(e)(4)(A)(ii). A "report" is "something that gives information" or "a 'notification.'" *Schindler Elevator*, 563 U.S. at 407–08. If the PTO were to publish a bound volume detailing its decision concerning a particular patent application, that would clearly constitute a federal report. And that is precisely what PAIR does. *See* Br. 19–21. PAIR's online accessibility only weighs in favor of triggering the bar.

Recognizing PTO reports published on PAIR as covered federal reports also promotes the public disclosure bar's purpose: preventing parasitic lawsuits. As with FOIA,

> anyone could have [obtained the same facts] and then filed the same suit. Similarly, anyone could identify a few regulatory filing and certification requirements, [search PAIR] until he discovers a federal contractor who is out of compliance, and potentially reap a windfall in a *qui tam* action under the FCA.

Schindler Elevator, 463 U.S. at 413. *Schindler*'s reasoning controls here, and Relator cites no authority that the 2010 Amendments otherwise changed what "report" means.

Instead, Relator fixates not on PAIR but PACER, lumping them together as "docket sheets" that would swallow the government-party restriction. Opp. 12. That, as explained, is nonsense. As the reporting system for adjudicative proceedings covered under Channel (i), PACER filings are necessarily subject to the government-party restriction. Information published through PAIR, conversely, reflects the PTO's administration of its statutory charge to manage the patent system

and reports the federal hearings integral to that charge.

3. Transactions And Allegations Published In Print And Online Journals, Newspapers, And Other Sources Constitute "News Media" Triggering The Bar.

Relator does not dispute that many (if not most) of his underlying facts were published previously in a wide variety of sources. Opp. 21. Instead, he attempts to limit "news media" to traditional journalism. *See* Opp. 19–20. But the Supreme Court long ago recognized that news, press, and the like cover a wide range of publications, *Lovell v. City of Griffin*, 303 U.S. 444, 452 (1938), a prescient decision as sources of news and information have since proliferated.

Unsurprisingly, the "general consensus in the federal courts" is that "news media" goes beyond "traditional[]" news sources, *U.S. ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, No. CV 17-1694 PSG, 2019 WL 3282619, at *13 (C.D. Cal. July 16, 2019), *rev'd on other grounds*, No. 19-56367, 2021 WL 1233378 (9th Cir. Mar. 31, 2021), and includes "information contained on publicly available websites," *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04-CV-1556, 2011 WL 3875987, at *7 (M.D. Pa. Sept. 1, 2011) (collecting cases). Although Relator dismisses this as "a special, extra-broad interpretation of the phrase," Opp. 20, courts have repeatedly and broadly held that "news media" captures targeted or curated sources of information including scholarly journals, scientific studies, business articles, competitor websites, and data collected and disseminated by the Government through websites and databases. Br. 21–22.

Relator's argument that Congress would have added "[i]nternet" to the statute had it intended online sources to qualify, Opp. 20, is reductive.[3] By that logic, Congress should have also specified "newspapers," "magazines," or "news cable" in the text. Instead, the 2010 Amendments maintained the "news media" channel without change, notwithstanding a consistent

[3] As the Supreme Court recently instructed, courts are "best served by focusing on the language [Congress] *did* employ" when interpreting statutes. *BP p.l.c. v. Mayor of Baltimore*, 141 S. Ct. 1532, 1539 (2021).

trend of judicial opinions interpreting that phrase expansively. *See Lorillard v. Pons*, 434 U.S. 575, 581 (1978) (Congress presumed to be aware of existing interpretations when reenacting a statute without change). Relator offers no reason to depart from that established understanding.

B. Relator's Material Allegations And Transactions Were Publicly Disclosed.

Relator's "allegations" of wrongdoing and the underlying "transactions" that "raise[] an inference of fraud consist[ing] of both the allegedly misrepresented facts and the allegedly true state of affairs" were clearly and previously publicly disclosed. *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018); *see also* Appendix A to Br. Relator tries to sidestep the bar by contending that every step in his daisy-chain theory must have been publicly disclosed for the bar to apply. Opp. 6, 8–10. That is wrong. Only the alleged fraud that forms the basis for the allegedly false claim for payment must be publicly disclosed, 31 U.S.C. §3730(e)(4)(A), as that is the misconduct that would alert the Government to review the veracity of those claims for payment.

Next, Relator argues that prior disclosures were insufficiently specific to trigger the bar. Opp. 5. Relying on a Sixth Circuit opinion, he contends that changing the §3730(e)(4)(A) threshold for disclosure from "based upon" to "substantially similar" "demand[ed] a greater degree of similarity" between the complaint and the public disclosures. Opp. 5. The Third Circuit has already explained that this change "merely codified the law as it already existed in this Circuit." *Omnicare, Inc.*, 903 F.3d at 84 n.6 (citing *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2017)). Relator dismisses this as dicta because no party in that case argued otherwise. Opp. 6 & n.2. A circuit court reciting its own established law, not contradicted by the parties, is not spouting dicta but establishing the analytical framework for its opinion. The Court should reject Relator's invitation to ignore *Omnicare* in favor of out-of-circuit law.[4]

[4] Relator's suggestion that Sixth Circuit law allows fraud allegations to proceed unless those allegations were previously disclosed as fraud, Opp. 6, 10 (citing *U.S. ex rel. Holloway v.*

Relator once again ignores the Third Circuit's "X+Y=Z" analytical framework. Our Initial Brief documented in detail the prior public disclosure of Relator's allegations and transactions supporting this approach. Br. 8–14; Appendix A to Br. Relator does not engage with, let alone dispute, the vast majority of these prior disclosures. Instead, Relator quibbles that the IPR petitions never actually used the word "fraud" and therefore did not disclose his present allegations of fraud. That is incorrect thrice over: *first*, no authority requires that degree of congruity; *second*, IPR petitioners may not raise fraud claims; and *third*, the IPR petitions did refer to the PTO as being "misled," based on the same facts Relator now dubs fraud. *See* RJN (Dkt. 128-4), Ex. D at 21, 51, 53; Ex. E at 22, 52–53; Ex. F at 63–64. That is more than sufficient for disclosure.

Relator also claims "one of the most important allegations of fraud"[5]—that Xtandi had not obtained FDA approval for chemo-naïve patients at the time of the market comparison—was not revealed in any of the disclosures. Opp. 8. Even if this "Z" had not been disclosed, the "X" and "Y" were, which is sufficient. *Omnicare*, 903 F.3d at 84. The alleged true state of affairs was known and published in the "Drugs@FDA" database, which provides "patient information, labels, approval letters, reviews, and other information" on approved drug products. *See* https://www.fda.gov/drugs/drug-approvals-and-databases/about-drugsfda. Xtandi's approval status was also identified in patent submissions, RJN Ex. C at 41, 58 (PDF pages), and in contemporaneously

---

Heartland Hospice, Inc., 960 F.3d 836 (6th Cir. 2020)), lacks support. *Heartland* disclaimed use of the word "fraud" and required only an inference of wrongdoing be disclosed. 960 F.3d at 844.

[5] Relator's Opposition adds new "facts" and "transactions" that are, in actuality, allegations of fraud. For instance, Relator alleges that "the listing in the Orange Book was improper" and that "the market price of Zytiga was inflated by an unlawful patent monopoly," Opp. 10–11—all of which depend on, and cannot be disentangled from, the predicate alleged fraud on the PTO. Relator also contends that Defendants did not identify public disclosures for these "other 'transactions'"; but, the Orange Book, the FSS, and the federal pricing processes constitute federal reports and hearings. *E.g. U.S. ex rel. Ambrosecchia v. Paddock Labs. LLC*, No. 4:12cv2164, 2015 WL 5605281, at *6 (E.D. Mo. Sept. 23, 2015) (Orange Book triggers bar). Relator suggests that claiming the acts were "improper" renders them undisclosed, but each of the alleged omissions or misrepresentations and the allegedly true state of affairs from which Relator drew his "improper" conclusion (i.e., the "X" and "Y") were disclosed. *See* Appendix A to Br.

published materials, *id.* Exs. PP, QQ, RR. The allegedly misrepresented facts were also identifiable through Defendants' patent submissions, *id.* Ex. C, as even Relator concedes, Opp. 10 (arguing it would have been "difficult" "for anybody to notice those twin missing facts"). The prior public disclosure of Relator's allegations and the underlying transactions bar his claim.

C. Relator Fails To Plead That He Is An Original Source.

Relator cannot escape the public disclosure bar as an original source. The SAC pleads no facts independent of, or that add materially to, the public disclosures. Br. 22–23. The one specific fact discussed in the Opposition, Xtandi's approval status, was adequately disclosed. *Supra* p.10. Relator otherwise offers only conclusory assertions that he "add[ed] 'significant specific details,'" which required "substantial expertise" that are "independent of and materially adds to any public disclosure." Opp. 22. Contrary to the Opposition, courts routinely adjudicate original-source questions at the motion-to-dismiss stage, *e.g.*, *Repko*, 2011 WL 3875987, at *17, and the Court should do so here. Mouthing the pleading standard is insufficient to survive dismissal and, despite three complaints and two prior motions to dismiss, Relator still cannot identify any relevant independent knowledge. Relator's concession that he "piece[d] together the fraud from many different … sources," Opp. 22, only underscores the futility of any further attempt to amend.

II. RELATOR FAILS TO PLEAD ESSENTIAL ELEMENTS OF HIS CLAIMS

A. Relator Fails To Plead A False Claim For Payment.

A false claim for payment is "the *sine qua non* of [an FCA] violation." *U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 124 (W.D. Pa. 2006). As discussed in the Initial Brief, Relator insufficiently pleaded a recognized theory of falsity. Br. 24–33. The theories advanced in the Opposition make clear that Relator's claims of falsity are untethered to any claim for payment and improperly treat the FCA improperly as an all-purpose fraud statute.

1. Relator Fails To Plead An Implied False Certification

To plead implied false certification, Relator must identify "specific representations about the goods or services provided" and "misleading half-truths" from a "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Id.* at 2001; Br. 24–26. He pleads neither.

First, Relator fails to identify any specific representations. Opp. 28–29. In *Escobar*, the defendant submitted claims using codes and numbers tied to particular services and providers, directly and falsely implying the provision of the same. *Escobar*, 136 S. Ct. at 2000–01. Relator here contends that Defendants' "claims for payment implicitly certified that the price was reasonable." Opp. 28. This approach would swallow *Escobar*'s rule, encompassing any claim for payment no matter how remote the alleged fraud and regardless of any specific representations. Defendants' claims for payment here reflected nothing more than the agreed contract price.

Recognizing this, Relator argues that no "specific representations" are necessary when claiming "inaccurate market prices." Opp. 30–31. But Relator's authorities, *Garbe* and *Strauser*, did not concern implied false certifications but rather the claiming of objectively inaccurate prescription drug prices. Relator's only other case, *U.S. ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392 (D.N.J. 2019), is irreconcilable with *Escobar* and its progeny. Br. 25–26. Even in *Bayer*, the court found a false implied certification by operation of law under the Anti-Kickback Statute. 376 F.3d at 408. Relator here contends that, in seeking payment, Defendants impliedly certified that the contractual price was "fair and reasonable" and that the patent was valid. Opp. 28–30. Neither *Escobar* nor its progeny allow so remote a theory of implied certification.

Second, the "fair and reasonable" requirement cannot bear the weight Relator puts on it. In the federal pricing scheme, it results from a government formula, not a subjective price examination. Br. 27–29. Relator does not dispute Defendants' description of the pricing process,

and assumes without support that government officers examine the patents' impact on price. Opp. 29. Relator cites *Allergan*, but that case also assumed without support that claims for reimbursement "certif[ied] that the prices of the drugs they were listing were 'fair and reasonable,'" and similarly failed to review the price-setting process or the irrelevance of patent validity in that process. *Silbersher v. Allergan Inc.*, No. 18-cv-03018, 2020 WL 7319407, at *37 (N.D. Cal. Dec. 11, 2020), *appeal docketed*, No. 21-15420 (9th Cir. Mar. 10, 2021). Neither *Allergan* nor Relator address that the federal pricing officer, not the manufacturer, certifies a price as fair and reasonable. Br. 27–28.

The Opposition otherwise proves too much. Relator dismisses as irrelevant that federal contracting officers never consider patent validity. Opp. 28–29. But if patent validity is irrelevant to pricing, then claiming reimbursement at the FSS price implies nothing about patent validity. Similarly, Relator misunderstands the pricing scheme he claims to vindicate. He cites 48 C.F.R. §15.402(a)(2)(i) for the proposition that "fair and reasonable" pricing assumes "adequate price competition." Opp. 30. But that regulation does not apply to "orders placed against" FSS contracts, including for Zytiga. 48 C.F.R. §8.404(a). In fact, FSS contract documents bar the Government from examining the bases for manufacturers' commercial price, RJN Ex. H at 53; Br. 28, confirming the commercial price serves only as a numerical basis to apply a discount.

In sum, Relator has failed to identify any affirmative representations, half-truths, or misleading omissions to support an implied false certification theory.

2. Relator Fails To Plead A "Promissory Fraud" Theory Of Falsity Based On A Purported Fraud On The PTO.

Promissory fraud is rooted in contract law and requires a close causal connection between the underlying fraud and presentation of a claim for payment. Br. 30–31. Relator concedes that "in some circumstances, the connection between an antecedent fraud and a later claim for payment

may be too attenuated." Opp. 27. This is that case, as Relator's promissory fraud theory rambles too far afield to be cognizable.

The Third Circuit has not applied promissory fraud outside the contract context. Br. 30–31. Relator asserts there "is no textual basis to limit fraud-in-the-inducement claims to contracts," pointing to the statutory definition of "claim" as being made pursuant to a contract or otherwise. Opp. 26. This confuses the elements of an FCA claim. Certainly a *claim* for payment may arise in the absence of a contract; but whether that *claim* is false is a different question.[6] Promissory fraud may render a claim false, but the Third Circuit has applied that theory only to claims made pursuant to a contract. *Plavix* demonstrates why; non-contract situations lack "the same *direct* causal connection between Defendants' alleged fraud … and the submission of false claims that is present between contracts induced by fraud and claims submitted under those contracts." *In re Plavix Mktg., Sales & Prods. Liab. Litig.*, 332 F. Supp. 3d 927, 952 (D.N.J. 2017). *Plavix*'s reasoning similarly applies here, where a contract also is lacking.

Indeed, Relator's authorities mostly feature direct causal relationships between "false certifications in enrollment or application forms … where claims are subsequently presented pursuant to the fraudulently induced relationship with the government." *Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 310-11 (E.D. Pa. 2017). In *Campie*, for example, the defendant purportedly lied to the Government to secure approval of a drug, which approval directly triggered eligibility for government payments. Br. 32; *see also U.S. ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365, at *9–10 (E.D. Pa. Apr. 12, 2017) (defendant "made expressly false statements to the FDA for approval … to induce Medicare and Medicaid payments"). Likewise, *Hendow* concerned an agreement to abide by certain rules to receive federal payments, and the

[6] For this reason, Relator's observation that the FCA was intended to reach those who lack a direct contractual relationship with the Government, Opp. 26, is beside the point.

university's misrepresentation made it eligible for payments pursuant to that agreement. *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1168–69 (9th Cir. 2006); Br. 32. And *U.S. ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005), concerned a two-step application process where the Seventh Circuit held the university could not rid itself of fraud in the first stage when the second-stage application specifically relied on the first-stage certification.[7]

None of these cases is on point. Relator has not pled that Defendants supplied wrong or inaccurate pricing data; sold the Government drugs that performed less than expected; or that federal officials inquired into, or viewed as material, Defendants' patent's validity (unlike the FDA asking the *Campie* defendant for specific representations about ingredient sources). And a patent prosecution does not result in a contract; cause any subsequent FDA approval; trigger eligibility to list a drug on the FSS; or induce any submission of a claim for reimbursement.[8] Relator makes passing reference to the Master Agreement and Pharmaceutical Pricing Agreement, Opp. 25, but has pled no facts to support a claim that Defendants fraudulently induced either. Relator has not identified any statute, regulation, or contract term showing that patent status is ever considered in the contracting process, let alone "integral" to eligibility for payment. *See also* Br. 32.[9]

3. Patent Prosecutions Are Not False Claims Actionable Under The FCA.

Relator asserts a new theory that appears nowhere in the SAC (or its predecessors): that the patent application itself was a false claim. Opp. 32–33. This Opposition Brief "Hail Mary" is

[7] Relator's other cases, such as *Garbe*, concern express falsity, which is analyzed differently. So too, *U.S. ex rel. Krahling v. Merck & Co.*, a classic case of factual falsity, where the defendant lied about the efficacy of its vaccine, sold it with false labeling, and concealed information material to the Government's payment decision. 44 F. Supp. 3d 581, 594–95 (E.D. Pa. 2014).
[8] None of these is the foreseeable result of the issuance of a patent to satisfy even the "substantial factor" proximate-causation approach Relator proposes. Opp. 27–28.
[9] The *Allergan* decision, on certified interlocutory appeal, similarly failed to grapple with any of this and therefore lacks persuasive value. Also unavailing is *Amphastar Pharmaceuticals Inc. v. Aventa Pharma SA*, No. EDCV-09-0023, 2012 WL 5512466 (C.D. Cal. Nov. 14, 2012). The court dismissed the complaint for failing to allege the submission of a claim, *id.* at *11–13, and the Ninth Circuit later affirmed a dismissal under the public disclosure bar. *See* 856 F.3d 696 (9th Cir. 2017).

improper and wrong. *See Jannarone v. Sunpower Corp.*, No. 18-9612, 2018 WL 5849468, at *2 (D.N.J. Nov. 7, 2018) (plaintiff may not amend complaint through his opposition).[10]

Relator argues without support that because patents are intellectual property, a patent application must be a claim for property. Opp. 32. But the FCA targets claims for payment, and a patent application seeks a patent not a payment. Even if patents were construed as payments under the FCA, albeit unsupported, a patent that has not yet issued is not government property; as Relator admits, it simply does not yet exist. Opp. 33 n.15. Because it has no value to the Government, its issuance occasions no loss. *See, e.g.*, *Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 109 (3d Cir. 2002) (application not resulting in authorization of federal funds not a claim under the FCA); *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182–84 (3d Cir. 2001) (submission of fraudulent legal bills for bankruptcy court approval does not implicate financial loss to the United States and falls outside the FCA (citing cases)).

Applicants may petition the Government for many different sorts of assignable rights that are subsequently treated as property but the issuance of which inflicts no corresponding economic loss on the Government. Relator's theory would expand the FCA to reach all such programs no matter how attenuated from the presentation of a claim for payment. This would not promote the FCA's purpose to protect the public fisc. It should be rejected.

B. Relator Fails To Plead Materiality.

The SAC fails to meet *Escobar*'s "demanding" materiality standard. Br. 33–35. Relator posits that any effect on price is *per se* material, Opp. 35,[11] but again this proves too much. Some

[10] Relator claims Defendants cannot address this theory because it was not refuted in the Initial Brief. Opp. 32 n.13. That brief addressed the theories of liability in the SAC—of which this is not one. Relator sought to raise this theory of liability in his prior Opposition, and it was equally unpled and improper then. Relator could have, but did not, petition to further amend his complaint. Having raised it improperly in a prior round of briefing does not make it any less waived.

[11] Respecting *Escobar*, Opp. 33, Relator has not pled facts suggesting (1) the Government has expressly identified patent validity as a condition of payment; (2) the Government has consistently

price increases could lead the Government to reject payment; others would not. Relator must plead facts demonstrating that the misconduct he alleges is material; he has not done so.

Three complaints in, Relator has yet to identify any statute, regulation, or other requirement that conditions a federal drug price, or reimbursement at that agreed price, on patent validity.[12] Rather, Relator merely speculates as to what the Government would *prefer*. Opp. 34. But here, the Government established a process for determining what it would pay, including identifying the criteria upon which it bases its pricing and reimbursement decisions. The only permissible, non-speculative inference as to what the Government *prefers* is the approach set out in the Government's pricing regulations, which make no provision respecting patents. Relator's musings to the contrary fall far short of any required pleading standard. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). And Relator's invocation of sundry enforcement tools listed in the SAC cuts against his claims, as the Government has not elected to use them here. Opp. 34 & n.16.

Relator's string cite, Opp. 35, shows how price *can* be material in particular contexts—such as when agency rules identify specific requirements relating to price—and does not support a *per se* rule about price regardless of the relevant regulatory context. Such a rule would be at odds with *Escobar*'s "rigorous" materiality standard. In *Ruckh v. Salus Rehab., LLC*, for example the defendant allegedly inflated the amount of services provided to patients—"a simple and direct theory of fraud"—an impermissible effort to maximize the amount of reimbursement—also "a fairly straightforward case"—under Medicare. 963 F.3d 1089, 1105 (11th Cir. 2020). This direct fraud inflated the price and involved "plain and obvious materiality." *Id.*

---

refused to pay for drugs whose patent is under challenge or was otherwise invalidated or held unenforceable; (3) noncompliance with patent-related laws is minor or significant. *See U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018).

[12] Relator's assertion that Defendants' PTO submissions were material to the agency's patenting decision, Opp. 34, is irrelevant because a patent application cannot constitute a false claim, *supra*.

The Government's continued payment can also be strong evidence of non-materiality. *Escobar*, 132 S. Ct. at 2003–04. Relator does not dispute that the Government continues to reimburse claims for Zytiga despite having been alerted to Relator's allegations. Br. 31. And his suggestion that the Government "may have good reasons unrelated to materiality to" pay a claim, Opp. 36, simply misunderstands materiality. If the Government has good reasons to pay, despite some violation, then the violation is not material. Relator has not met his burden.

III. RELATOR FAILS TO PLEAD FRAUD ON THE PTO.

An FCA complaint based on a predicate violation of law must plead that violation. Br. 35–36. To avoid this rule, Relator insists that his claims "do not rely on 37 C.F.R. §1.56 as an 'underlying violation' in the same way that the Stark Act violation may be the basis for" FCA claims. Opp. 37. But the SAC repeatedly invokes 37 C.F.R. §1.56 and the duty of candor as the source of Defendants' alleged misconduct, *see, e.g.*, SAC ¶¶ 54, 82, 84, 84d–84e, 87, 87b–87i, and identifies no other duty that would require the disclosures he claims were withheld from the PTO.

The FCA does not "appl[y] by its own force" to Defendants' conduct before the PTO. Opp. 37. To be sure, "violations of statutory, regulatory, or contractual requirements" might be a basis for FCA liability. *Escobar*, 136 S. Ct. at 1999; *cf.* Opp. 36. But other than the duty of candor, Relator has not identified any statutory, regulatory, or contractual requirement Defendants allegedly violated. And although the FCA has its "own statutory scienter and materiality rules," Opp. 36, those govern the submission of claims for payment. Where a false claim turns on the upstream commission of some other fraud, the relator must plead that prior fraud, or the subsequent claims for payment are not false. The FCA does not supplant the legal elements of such upstream violations. *See U.S. ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019). The SAC either relies on the duty of candor, and Relator must adequately plead a violation of that duty, or he has not shown how the alleged omissions or misrepresentations can propel an FCA claim.

And Relator does not plausibly plead that Defendants fraudulently obtained the '438 Patent. *See* Br. 37–38. To plead a violation of the duty of candor—including as a predicate offense in a *Walker Process* antitrust claim—the challenger must identify the specific *individual* responsible for defrauding the PTO. Br. 36. Relator does not dispute this, and just refers cursorily to "the detailed pleading in ¶¶ 63 through 82 of the Complaint." Opp. 39. But the SAC identifies in passing only three individuals, *see* SAC ¶¶ 70–71, 91, without connecting inequitable conduct's elements, such as specific intent, to any of them. Br. 37. That does not satisfy Rule 9(b)'s high bar, *see Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011).

Relator next argues that "principals are [generally] liable for the fraud … [of] their agents." Opp. 39. Defendants do not contend otherwise, but Rule 9(b) requires facts "from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *Delano Farms Co.*, 655 F.3d at 1350. He does not do so. Relator's own authorities even focus on alleged conduct by specific individuals rather than the corporate entity. *See, e.g.*, *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010) ("Dr. Stoddard"); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1186 (Fed. Cir. 1995) ("Smith, Whitson, and Hirsh"). Relator has not pled the predicate fraud on which his entire case rests.

IV. ALL CLAIMS AGAINST BTG SHOULD BE DISMISSED WITH PREJUDICE

Relator concedes BTG's arguments, Opp. 38–39—namely, that his allegations: (a) comprise legally deficient group pleading, (b) violate Rule 9(b) and omit any allegations about BTG's alleged knowledge of the fraud or its unlawful conduct, and (c) fail to cite authority establishing how BTG could have caused an FCA violation merely by owning and enforcing a patent. The Court should dismiss all claims against BTG on these grounds, and neither of Relator's two opposition arguments cure these deficiencies.

First, Relator concedes BTG did not prosecute the '438 patent, vaguely claims BTG was "involved in all of that subsequent conduct," and asserts BTG could be jointly and severally liable with J&J. Opp. 40. Yet joint-and-several liability cannot establish liability; it only apportions it. *Cf.* Restatement (Third) of Torts: Apportionment Liab. § 12 (2000). Both cases that Relator cites, Opp. 40, undermine his argument and do not support FCA liability based on patent ownership. In both cases, joint-and-several liability was uncontested. In one, the court noted that the concept applied only "[w]here one or more persons have *committed* a fraud." *Mortgs., Inc. v. U.S. Dist. Court*, 934 F.2d 209, 212–13 (9th Cir. 1991) (emphasis added) (granting mandamus petition; ordering dismissal of counterclaim to plaintiffs' FCA complaint). In the other, the court noted that the concept applied "[w]here one or more persons have *acted together* to submit false claims." *United States v. Bourseau*, No. 03-cv-907-BEN (WMC), 2006 U.S. Dist. LEXIS 100313, at *36 (S.D. Cal. Sept. 29, 2006) (emphasis added). Relator failed to allege what BTG actually did; joint-and-several liability cannot cure that omission.

Second, challenged to identify authority that merely owning a patent could give rise to FCA liability, Opp. 40, Relator cites *In re Rembrandt Techs., LP Patent Litig.*, 899 F.3d 1254 (Fed. Cir. 2018), which is legally irrelevant and factually inapposite. Opp. 40. Relator seeks to impose liability under the FCA for allegedly false claims seeking reimbursement from government payors (about which *Rembrandt* says nothing), not for inequitable conduct at the PTO (as in *Rembrandt*, 899 F.3d at 1272–75) or fraudulently enforcing a patent in federal court. The Court should dismiss Relator's claims against BTG with prejudice.

CONCLUSION

For all the reasons set forth in the Initial Brief and this Reply, Relator's Second Amended Complaint should be dismissed with prejudice.

Dated: July 2, 2021

Respectfully submitted,

SILLS CUMMIS & GROSS P.C.

By: *s/ Jeffrey J. Greenbaum*
JEFFREY J. GREENBAUM
jgreenbaum@sillscummis.com
GREGORY E. REID
greid@sillscummis.com
One Riverfront Plaza
Newark, New Jersey 07102
Phone: (973) 643-7000
Facsimile: (973) 643-6500

SIDLEY AUSTIN LLP

GORDON D. TODD (*pro hac vice*)
gtodd@sidley.com
KIMBERLY LEAMAN (*pro hac vice*)
kimberly.leaman@sidley.com
1501 K Street, N.W.
Washington, DC 20005

Attorneys for Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson

WALSH PIZZI O'REILLY FALANGA LLP

By: *s/ Liza M. Walsh*
LIZA M. WALSH
lwalsh@walsh.law
KATELYN O'REILLY
koreilly@walsh.law
WILLIAM T. WALSH, JR.
wwalsh@walsh.law
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
Phone.: (973) 757-1100
Facsimile: (973) 757-1090

WHITE & CASE LLP

JACK E. PACE III (*pro hac vice)*
jpace@whitecase.com
ALISON HANSTEAD (*pro hac vice*)
ahanstead@whitecase.com
1221 Avenue of the Americas
New York, NY 10020-1095

PETER J. CARNEY (*pro hac vice*)
pcarney@whitecase.com
ADAM M. ACOSTA (*pro hac vice*)
adam.acosta@whitecase.com
701 Thirteenth Street, NW
Washington, DC 20005-3807

KEVIN M. BOLAN (*pro hac vice*)
kevin.bolan@whitecase.com
75 State Street
Boston, MA 02109-1814
Telephone: (617) 979-9311

Attorneys for Defendant BTG International Limited